



PATENT

Atty. Docket No.: 13024/35946

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:) I hereby certify that this paper is being
McMichael, J. <i>et al.</i>) deposited with the United States Postal
Serial No.: 09/495,186) Service with sufficient postage as first
Filed: February 1, 2000) class mail in an envelope addressed to:
) Assistant Commissioner for Patents,
) Washington, D.C. 20231 on this date:
)
For: TREATMENT OF SYMPTOMS) April 18, 2001 <i>JS</i> 4/18/01
OF ASTHMA, ALLERGIES AND) April 12, 2001
OTITIS MEDIA)
)
Group Art Unit: 1633) <i>Jeffrey S. Sharp</i>
) Jeffrey S. Sharp
Examiner: Wilson, M.) Registration No. 31,879
) Attorney for Applicants

DECLARATION OF VERNON DURIE V.M.D. UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

1. I, Vernon Durie am a doctor of veterinary medicine practicing in Cobleskill New York and am licensed by the State of New York. I received my B.S. in premedical studies from Fairleigh Dickenson University in Teaneck, N.J in 1968; my Masters in Animal Science from Rutgers University; and my V.M.D. from the University of Pennsylvania in 1973. Since then I have practiced veterinary medicine on both small and large animals including horses.

2. I submit this declaration to address certain issues raised in the Office Action dated October 18, 2000 in the above-identified application. In particular, I am informed that the Patent Office Examiner has raised questions of whether administration of DNA

containing compositions by methods other than by sublingual administration is effective to treat symptoms of allergies and asthma in subjects suffering from those diseases. In response to those questions I report that I have used the DNA containing compositions of the invention to effectively treat symptoms of allergies in horses and that I administered those compositions by the route of sub-cutaneous injection to the neck of the afflicted horse.

3. Horses are affected by a disease state known as "Heaves" which is a chronic obstructive pulmonary disorder (COPD) resulting from an allergic reaction to either mold spores in hay or pollen. Heaves is characterized by coughing, wheezing and a labored expiration from the lungs. Heaves is generally not associated with excess mucous production.

4. I have successfully treated eight to ten horses suffering from coughing, wheezing and labored expiration that I diagnosed with Heaves by subcutaneous administration with a composition identified to me as "SCTF" that I am informed contained 0.003 mg/mL (0.0006 mg per 0.2 mL dosage) of salmon DNA. Specifically, I injected 0.2 mL of the composition subcutaneously to the neck of each horse suffering from Heaves twice daily for one week followed by subcutaneous administration once daily for another week. In each horse that I had positively identified as suffering from Heaves I found that the symptoms of coughing, wheezing and labored expiration from the lungs were improved by treatment with the DNA containing compositions of the invention.

5. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.


Vernon Durie V.D.M.

April 12, 2001